

NEW JERSEY STATE PROFICIENCY TESTING PROGRAM YOUR SOURCE FOR 2004



PROVIDED THROUGH THE
DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL
LABORATORIES CLINICAL LABORATORY IMPROVEMENT SERVICE

PROGRAM INFORMATION FOR 2004

Test Menu Changes:

- Additions:** Automated Immunohematology (JAT) - CAP Review
Immunoassay-Parasites (P1) - CAP Review
Erythropoietin Survey (EPO) - CAP Review
Anti-HIV1 Antibody (RHIV) - CAP Review
Serum Drug Screen (SDS) - CAP Review
- Changes:** Rheumatoid Factor and/or Rubella Antibody Only Survey (S102) - Mailing Schedule Change
- Deletions:** Bacteriology (M100) and Gram Stains (M102)
CAP Hematology Survey (FH7)

Tear out Enrollment Forms and Mailing Schedules:

Find them in the center of the brochure
or download them from the web at:
<http://www.state.nj.us/health/phel/eep.htm>

Choose the Correct Form for your Facility:

Physician Office Laboratory CL64

Licensed Laboratory CL37

Not Sure ? Call 609-292-5607



State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PO BOX 361
TRENTON, N.J. 08625-0361

JAMES E. MCGREEVEY
Governor

www.state.nj.us/health

CLIFTON R. LACY, M.D.
Commissioner

Dear Doctor/Director:

We would like to take this opportunity to provide your facility with the New Jersey Department of Health and Senior Services (DHSS) 2004 Proficiency Testing Brochure.

The program offered through the Clinical Laboratory Improvement Service (CLIS) is designed to provide surveys in the many laboratory specialties, subspecialties and analytes requiring proficiency testing under state and/or federal regulation or rule. The CLIS Proficiency Testing Program is approved by the Center for Medicare and Medicaid Services (CMS) and COLA.

Good laboratory practice, regardless of the level of service offered patients, includes appropriate external comparative evaluation of the clinical tests the laboratory is approved to perform.

The program includes challenges in required analytes or procedures specified in CLIA regulations, and a Biannual Assessment Program (BAP) component to assist laboratories in establishing accuracy and reliability of certain procedures not included under CLIA's Subpart I, Proficiency Testing (Section 493.179).

We hope you will review the brochure and enroll in the most appropriate survey(s) to meet your level of service.

We look forward to serving you in the evaluation and improvement of your laboratory's performance.

Sincerely,

Alberta A. Prioleau
Supervising Clinical Laboratory Evaluator
Proficiency Testing Program
Clinical Laboratory Improvement Service

CONTENTS

PAGE

Program Information

1-2

PROGRAM INFORMATION

MICROBIOLOGY

Throat Culture Only	3
Group A Strep Throat Screen (DAT)	3
Group A Strep Throat Screen (DAT): CLIA Waived Methods	3
Urine Culture (UC) Screen: Colony Count Only	4
UC Screen with Antibiotic Susceptibility Testing	4
Dermatophyte Screen	4

DIAGNOSTIC IMMUNOLOGY

Syphilis	5
Diagnostic Immunology (ASO, IM, serum hCG, Rubella, RF)	5
Rheumatoid Factor/Rubella Antibody Only	5
ASO, Infectious Mononucleosis and/or serum hCG Only	6
Antinuclear Antibody	6
<u>H. pylori</u> Antibody	6
C-Reactive Protein (CRP)	7

ENDOCRINOLOGY

Endocrinology	7
Prostate Specific Antigen (PSA) and/or	
Prostatic Acid Phosphatase (PAP)	7

CHEMISTRY

Routine Chemistry	8
Lipids/Glucose Only	8
Blood Gas	9
Electrolytes Only	9
Whole Blood Glucose (CLIA Waived Methods)	9
Glycohemoglobin	9
Gamma Glutamyl Transferase (GGT) and/or Phosphorus	10

TOXICOLOGY

Erythrocyte Protoporphyrin	10
Drugs of Abuse in Urine	10
Therapeutic Drug Monitoring	11

HEMATOLOGY

CBC with Blood Cell ID	11
Hemoglobin and/or Hematocrit Only	11
Blood Cell Identification Only	12
QBC: Centrifugal Hematology with Differential	12
Erythrocyte Sedimentation Rate	12

COAGULATION

Coagulation	12
Whole Blood Prothrombin Time	13
CoaguCheck Prothrombin Time	13

CONTENTS

(Continued)

	PAGE
IMMUNOHEMATOLOGY	
Comprehensive Blood Bank/Immunohematology	14
Limited Immunohematology	14
URINALYSIS	
Dipstick Urinalysis Only	14
Urine hCG Only	14
Sperm Count	15
Urinalysis Combo: Dipstick, Microscopic and Urine hCG	15
Fecal Occult Blood	15
MICROSCOPY	
Urine Microscopy Only	15
KOH Prep	16
Pinworm Prep	16
Sperm (absence or presence)	16
Vaginal Wet Prep	16

THE NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES (DHSS) PROFICIENCY TESTING PROGRAM

HISTORICAL BACKGROUND

For more than 25 years the Department's Clinical Laboratory Improvement Service (CLIS) has served New Jersey's licensed laboratories in proficiency testing (PT). Since 1991, the Program has obtained the annual approval granted to proficiency testing providers through the Center for Medicare and Medicaid Services (CMS). Laboratories operating under CLIA '88 rules must enroll in a CMS approved program. COLA has also conferred approval on the Department's PT program for those laboratories seeking COLA accreditation.

A highly qualified, professional staff is available to answer technical or administrative questions concerning proficiency testing. Their many years of bench-level experience, documented success in improving laboratory performance through proficiency testing and convenient location complements a comprehensive laboratory evaluation package.

PROGRAM PARTICIPATION

The New Jersey State Sanitary Code, Chapter IV Laboratories, Regulation 5(a) mandates that all New Jersey licensed laboratories participate in proficiency testing surveys in all areas for which they are licensed and that the Department has deemed available.

The Federal Clinical Laboratory Improvement Amendments (CLIA '88) also mandate enrollment and successful participation in a CMS approved proficiency testing program. Laboratories possessing a federal CLIA certification and limited to performing tests designated as "waived" are exempt from this requirement. However, good laboratory practice includes some method of quality assessment to be performed regularly.

Laboratories possessing a state license are required to perform proficiency testing on analytes added after February 28, 1992 to the CLIA list of waived tests.

New Jersey laboratories serving a practice of 5 or more physicians are also required to obtain a New Jersey clinical laboratory license under current state regulations in addition to CLIA certification.

SURVEY SELECTION

This brochure is designed to provide information relative to the laboratory specialties mandated by state and/or federal regulations and available from the Department's CMS approved program. It contains a full range of surveys to accommodate the needs of a wide spectrum of laboratories ranging from the physician office to the university hospital.

The **DHSS Proficiency Testing Program** includes laboratory evaluation surveys in the mandated specialties of microbiology, diagnostic immunology, immunohematology, endocrinology, chemistry, toxicology, hematology and coagulation. An approved PT evaluation survey in regulated areas includes three annual testing events with five challenges per event in each of the required analytes or test procedures. Surveys for the Department's **Biannual Assessment Program (BAP)** are also included for your convenience and enrollment should be considered to provide complete compliance with CLIA regulations.

For New Jersey participants, the PT application which accompanies this brochure includes all mandated proficiency testing areas available through the DHSS and approved alternative providers and corresponding fees for both. **There is no registration fee required for enrollment in the New Jersey Department of Health and Senior Services PT Program.** If the need for samples occurs outside the routine survey schedule, every attempt will be made to provide laboratories with additional material. A processing fee of \$50 per sample set will be assessed for this service.

When New Jersey licensed laboratories enroll in an approved alternative program for mandated surveys, they must instruct their proficiency testing provider, in writing, to forward copies of evaluated results to the Department's Clinical Laboratory Improvement Service. A \$50 fee per survey will be imposed for enrollment with an approved alternative provider to cover the cost of documenting and confirming enrollment, monitoring performance and providing the needed follow-up action and correspondence with participants. Should the need for samples arise outside the routine schedule for surveys provided through alternate PT programs, the PT provider should be prepared to provide additional material upon request.

NON-SCHEDULED PROFICIENCY TESTING

Pre-Licensure

All laboratories seeking State licensure will be required to perform testing in the specialty, subspecialty or analyte for which they are requesting approval when proficiency testing is available. The fee for pre-licensure PT sample sets obtained from this provider is \$50 and includes four to five samples depending on the particular test requested.

If the need for pre-licensure PT samples occurs which is outside the availability of the NJDHSS PT Program and requires laboratory evaluation through an external PT provider a fee of \$50 per sample set, payable to the Department, will be assessed for review of the data.

Adverse Action

Laboratories who fail to maintain a level of successful performance (satisfactory performance in 2 of the 3 most recent PT surveys) for compliance with either State or federal regulations or rules may face possible "adverse action". The process of "adverse action" requires the laboratory to demonstrate its ability to perform the test(s) in question on additional PT material prior to any proposed suspension of State licensure or federal certification. Additional PT material may be purchased from the NJDHSS PT Program for a fee of \$50 per set. If the need for "adverse action" PT samples occurs outside the availability of the NJDHSS PT Program and requires evaluation through an external PT provider, a fee of \$50 per sample set, payable to the Department, will be assessed for review of the data.

SURVEY EVALUATION

After participation in a DHSS proficiency testing survey, the laboratory will receive an evaluated copy of the results they submitted to the program. It will indicate both an overall score for the survey and, when applicable, a score for each analyte in the survey which is the analyte score. In addition to the enrollee's personal evaluation, a summary report of the entire survey is compiled to provide the enrollee an opportunity to compare their results with those of other methods or instruments.

When indicated by the participant on the PT enrollment application, the laboratory's scores will be forwarded to CMS as required of PT providers under CLIA '88. If a laboratory has chosen to obtain CLIA accreditation through a deemed status organization, a copy of the enrollee's performance evaluation will be provided, if requested, to the accrediting agency.

ENROLLMENT

Review this brochure and enroll in the most appropriate survey(s) to meet the level of service provided for your patients.

Complete the Proficiency Testing Program Selection Form and return it no later than **November 12, 2003** with the required fees (make check payable to NJDHSS-PT) and forward to the:

New Jersey Department of Health and Senior Services
Clinical Laboratory Improvement Service
Attn: PT Program Coordinator
P.O. Box 361
Trenton, NJ 08625-0361

Laboratories submitting renewal applications after November 12, 2003 will be assessed a late fee of \$50.

Please provide separate checks for licensure and proficiency testing when forwarding your applications.

Cancellation Policy

Credit will be issued for cancelled survey shipments if the participant provides CLIS written notification six(6) weeks prior to the next scheduled shipping date for the cancelled survey(s). A processing fee of \$25 will be implemented for all cancellation requests submitted after January 1, 2004.

A NJ licensed facility which fails to enroll in a Department approved PT program by December 31, 2003 and performs patient testing after January 1, 2004 is considered to be in violation of N.J.A.C. 8:44-2.5(b). Pursuant to N.J.S.A. 45:9-42.43, the delinquent laboratory may be subject to a penalty of up to \$1,000.00 for each violation.

If you desire additional information or have questions regarding the DHSS Proficiency Testing Program please contact the Clinical Laboratory Improvement Service at 609-292-5605, option 3.

MICROBIOLOGY

Survey M101

Analyte:

Detection of Group A beta
hemolytic Streptococcus using
Bacitracin/Agar plate method

Shipping Dates:

TC-1-04	5/04
TC-2-04	8/04
TC-3-04	11/04

**Throat
Culture Only**
Price: \$150

Sample Type:

Each shipment will include five commercially prepared swabs.

Analyte:

Detection of Group A beta hemolytic
Streptococcus using rapid identification
(swab) methods

Shipping Dates:

TS-1-04	2/04
TS-2-04	5/04
TS-3-04	10/04

Survey M103

**Group A Strep
Throat Screen**
(Direct Antigen Test)
(Rapid Strep)
Price: \$100

Sample Type:

Each shipment will include five formalinized throat swabs.

Analyte:

Detection of Group A beta hemolytic
Streptococcus using CLIA waived Direct
Antigen Test (DAT) methods

Shipping Dates:

6/04
11/04

Survey B113+

**Group A Strep
Throat Screen (DAT)**
CLIA Waived Methods
Price: \$25

Sample Type:

Each shipment will include two formalinized throat swabs.

**THIS SURVEY IS NOT ACCEPTABLE FOR USE BY LABORATORIES
POSSESSING A NEW JERSEY CLINICAL LABORATORY LICENSE.**



MICROBIOLOGY

Survey M104+

**Urine Culture
Screen**
Price: \$75

Analyte:

Colony Count

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two lyophilized samples.

Survey M105 +

**Urine Culture Screen with
Antibiotic
Susceptibility Test**
Price: \$100

Analyte:

Colony count with Antibiotic Susceptibility
Testing will be included for 3 out of 4
samples shipped during the year.

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two lyophilized samples.

Survey M400 +

Dermatophyte Screen
Price: \$75

Analyte:

Presence or absence of dermatophytes.

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two commercially prepared swabs containing material for those laboratories screening for dermatophytes using DTM agar.

+ PARTICIPANT RESULTS FOR BIENNIAL ASSESSMENT SURVEYS, (IDENTIFIED BY THE "+") WILL NOT BE REPORTED TO CMS. HOWEVER, PARTICIPATION WILL SATISFY CMS REQUIREMENTS FOR EXTERNAL ASSESSMENT OF ANALYTES NOT INCLUDED UNDER SUBPART I, PROFICIENCY TESTING PROGRAMS SECTION 493.1709.

DIAGNOSTIC IMMUNOLOGY

Survey S100

Analyte:

Qualitative determination of
the syphilis antibody

Shipping Dates:

SS-1-04	4/04
SS-2-04	8/04
SS-3-04	12/04

Syphilis

Price: \$150

Sample Type:

Each shipment will include five serum based samples for qualitative determination.

Survey S101

Analytes:

Antistreptolysin O (ASO)
Infectious mononucleosis (IM)
Serum hCG
Rubella antibody
Rheumatoid factor

Shipping Dates:

DI-1-04	2/04
DI-2-04	6/04
DI-3-04	9/04

**Diagnostic
Immunology**
(ASO, IM, Serum hCG
Rubella, RF)
Price: \$340

Sample Type:

Each shipment will include five serum based samples for qualitative determination.

Survey S102

Analytes:

Rheumatoid factor
Rubella antibody

Shipping Dates:

DI-1-04	2/04
DI-2-04	6/04
DI-3-04	9/04

**Rheumatoid Factor
and/or
Rubella
Antibody Only**
Price: \$280

Sample Type:

Each shipment will include five serum based samples for qualitative determination.



DIAGNOSTIC IMMUNOLOGY

Survey S103

**ASO, Infectious
Mononucleosis or
Serum hCG Only**
Price: \$280

Analytes:

Antistreptolysin O (ASO)
Infectious mononucleosis (IM)
Serum hCG

Shipping Dates:

DI-1-04	2/04
DI-2-04	6/04
DI-3-04	9/04

Sample Type:

Each shipment will include five serum based samples for qualitative determination.

Survey S104

**Antinuclear
Antibody**
Price: \$285

Analyte:

Antinuclear antibody

Shipping Dates:

DI-1-04	2/04
DI-2-04	6/04
DI-3-04	9/04

Sample Type:

Each shipment will include five serum based samples for qualitative determination of the antibody.

Survey B105+

**H. pylori
Antibody**
Price: \$75

Analyte:

Presence or absence of H. pylori antibody
in serum, plasma or whole blood.

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two serum based samples for qualitative determination of the antibody.

DIAGNOSTIC IMMUNOLOGY

Survey B106+

Analyte:

C-Reactive Protein

Shipping Dates:

6/04
11/04

**C-Reactive
Protein (CRP)**
Price: \$35

Sample Type:

Each shipment will contain two serum based samples for qualitative determination.

ENDOCRINOLOGY

Survey E100

Analytes:

Cortisol
T-3 Uptake
Thyroxine (free and total)
Triiodothyronine
TSH

Shipping Dates:

E-1-04 3/04
E-2-04 7/04
E-3-04 11/04

Endocrinology
Price: \$190

Sample Type:

Each shipment will include five liquid serum samples for quantitative determination.

Survey B107+

Analytes:

PSA and/or PAP

Shipping Dates:

6/04
11/04

**Prostate Specific
Antigen (PSA)
and/or
Prostatic Acid
Phosphatase (PAP)**
Price: \$75

Sample Type:

Each shipment will include two lyophilized samples for quantitative determination of PSA and/or PAP.



CHEMISTRY

Survey C100

**Routine
Chemistry**
Price: \$275



Analytes:

ALT/SGPT
Albumin
Alkaline phosphatase
Amylase
AST/SGOT
Bilirubin (total)
Calcium (total)
Chloride
Cholesterol (total)
HDL cholesterol
Creatine kinase
Creatinine
Iron
Glucose
LDH
Magnesium
Potassium
Sodium
Total protein
Triglycerides
Urea nitrogen
Uric acid

Shipping Dates:

C-1-04	3/04
C-2-04	7/04
C-3-04	11/04

Sample Type:

Each shipment will include five liquid serum samples for quantitative determination depending on the analyte testing performed on patient samples.

Survey C101

**Lipids/Glucose
Only**
Price: \$175

Analytes:

Cholesterol (total and/or HDL)
Triglycerides
Glucose

Shipping Dates:

C-1-04	3/04
C-2-04	7/04
C-3-04	11/04

Sample Type:

Each shipment will include five liquid serum samples for quantitative determination depending on the analyte testing performed on patient samples.

CHEMISTRY

Survey C102

Analytes:

pH
PO₂
PCO₂

Shipping Dates:

BG-1-04 4/04
BG-2-04 7/04
BG-3-04 11/04

Blood Gas

Price: \$200

Sample Type:

Each shipment will include five aqueous based samples for quantitative determination. Surveys are required for each primary testing instrument in the facility.

Note: Aqueous based PT samples are appropriate for use with both aqueous and fluorocarbon based blood gas instruments.

INCLUDE NUMBER OF SURVEYS (NS) NEEDED IN COST CALCULATIONS ON PROFICIENCY TESTING ENROLLMENT FORM.

Survey C103

Analytes:

Sodium (Na)
Potassium (K)
Chloride (Cl)

Shipping Dates:

C-1-04 3/04
C-2-04 7/04
C-3-04 11/04

Electrolytes**Only**

Price: \$150

Sample Type:

Each shipment will include five liquid serum samples for quantitative determination depending on the analyte testing performed on patient samples.

Survey B108+

Analyte:

Glucose

Shipping Dates:

6/04
11/04

Whole Blood**Glucose**

(CLIA Waived Methods

Only)

Price: \$50

Sample Type:

Each shipment will include two stabilized human RBC samples for evaluation of waived methods only.

Survey B109+

Analyte:

Glycohemoglobin

Shipping Dates:

6/04
11/04

Glycohemoglobin

Price: \$50

Sample Type:

Each shipment will include two liquid hemoglobin hemolysate samples for the quantitative determination of HbA_{1c}.

CHEMISTRY

Survey B117+

**Gamma Glutamyl
Transferase (GGT)
and/or
Phosphorus**
Price: \$50

Analyte:

GGT and/or Phosphorus

Shipping Dates:

6/04
12/04

Sample Type:

Each shipment will include two liquid serum samples for quantitative determination of GGT and/or Phosphorus.

TOXICOLOGY

*Survey T100**

**Erythrocyte
Protoporphyrin**
Price: \$225

Analyte:

Erythrocyte protoporphyrin

Shipping Dates:

EP-1-04 1/04
EP-2-04 5/04
EP-3-04 9/04

Sample Type:

Each shipment will include five human blood samples for quantitative determination.

*Survey T101**

Drugs of Abuse
Price: \$250



Analytes:

Morphine (opiates)
Phencyclidine (pcp)
Amphetamine
Cocaine
Methadone
Barbiturates
Cannabinoids

Shipping Dates:

UT-1-04 3/04
UT-2-04 6/04
UT-3-04 9/04

Sample Type:

Each shipment will include five human urine based samples for qualitative determination.

***THESE ANALYTES ARE NOT REGULATED BY CMS. HOWEVER, ANYONE REQUESTING NJ STATE LICENSURE IN THESE AREAS MUST ENROLL AND PARTICIPATE SUCCESSFULLY.**

TOXICOLOGY

Survey T102

Analytes:

Carbamazepine
Digoxin
Lithium
Phenobarbital
Phenytoin
Theophylline
Valproic Acid

Shipping Dates:

TDM-1-04 3/04
TDM-2-04 7/04
TDM-3-04 11/04

Therapeutic Drug**Monitoring**

Price: \$320

This survey is not appropriate for laboratories performing regulated TDM analytes in addition to those listed above.

Sample Type:

Each shipment will include five liquid serum samples for quantitative determination.

HEMATOLOGY

*Survey H100***

Analytes:

White blood cell count
Red blood cell count
Hematocrit
Hemoglobin
Platelet count
Blood cell identification

Shipping Dates:

H-1-04 2/04
H-2-04 6/04
H-3-04 10/04

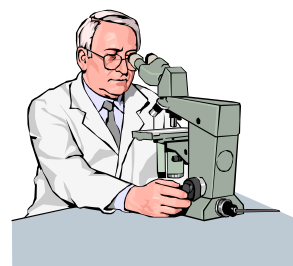
CBC with Blood**Cell ID**

Price: \$225

Sample Type:

Each shipment will include five whole blood samples for quantitative determination. Five 35mm transparencies per shipment for the identification of white blood cells, red blood cells and platelets will also be included if differentials are performed on patient samples.

****SURVEY NOT APPROPRIATE FOR USE WITH THE QBC INSTRUMENT OR AUTOMATED DIFFERENTIAL HEMATOLOGY ANALYZERS.**



*Survey H101***

Analytes:

Hemoglobin and/or
Hematocrit

Shipping Dates:

H-1-04 2/04
H-2-04 6/04
H-3-04 10/04

Hemoglobin**and/or****Hematocrit****Only**

Price: \$125

Sample Type:

Each shipment will include five whole blood samples for quantitative determination.

****SURVEY NOT APPROPRIATE FOR USE WITH THE QBC INSTRUMENT.**

HEMATOLOGY

Survey H102

**Blood Cell
Identification
Only**
Price: \$100

Analyte:

Blood cell identification

Shipping Dates:

H-1-04	2/04
H-2-04	6/04
H-3-04	10/04

Sample Type:

Each shipment will include five 35mm transparencies.

Survey H104

**QBC: Centrifugal
Hematology with
Differential**
Price: \$225

Analytes:

Hematocrit
Hemoglobin
Platelet Count
WBC
WBC differential (2-part)

Shipping Dates:

Q-1-04	2/04
Q-2-04	6/04
Q-3-04	10/04

Sample Type:

Each shipment will include five whole blood samples for quantitative determination.

Survey B103+

**Erythrocyte
Sedimentation
Rate**
Price: \$75

Analyte:

Erythrocyte sedimentation rate

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two samples of whole blood for the quantitative determination of sedimentation rate.

COAGULATION

Survey H103

Coagulation
Price: \$225

Analytes:

Prothrombin time (PT)
Activated partial thromboplastin time (APTT)
Fibrinogen

Shipping Dates:

H-1-04	2/04
H-2-04	6/04
H-3-04	10/04

Sample Type:

Each shipment will include five lyophilized plasma samples for quantitative determination.

**SURVEY NOT APPROPRIATE FOR USE WITH WHOLE BLOOD
ANALYZERS.**

COAGULATION

Survey H105

Analyte:

Prothrombin Time

Shipping Dates:

WBP-1-04	2/04
WBP-2-04	6/04
WBP-3-04	10/04

Whole Blood
Prothrombin Time
Price: \$175

Sample Type:

Each shipment will include five lyophilized blood samples with their corresponding diluent components for the quantitative determination of prothrombin time.

THIS SURVEY IS APPROPRIATE FOR STATE-LICENSED LABORATORIES THAT USE THE ROCHE DIAGNOSTIC COAGUCHEK S SYSTEMS TEST (SAME AS THE BOEH. MANN. & ROCHE DIAGNOSTICS) AND THE ROCHE COAGUCHEK PRO DM SYSTEM.

**Analyte:**

Prothrombin Time

Shipping Dates:

6/04
11/04

Survey B116+

CoaguChek
Prothrombin Time
Price: \$75

Sample Type:

Each shipment will include two lyophilized blood samples with their corresponding diluent components for the quantitative determination of prothrombin time.

THIS SURVEY IS APPROPRIATE FOR LABORATORIES THAT ARE CLIA APPROVED BUT NOT STATE-LICENSED. IT IS COMPATIBLE WITH THE ROCHE DIAGNOSTIC COAGUCHEK S SYSTEMS TEST (SAME AS THE BOEH. MANN. & ROCHE DIAGNOSTICS) AND THE ROCHE COAGUCHEK PRO DM SYSTEM.

IMMUNO- HEMATOLOGY

Survey I100

**Comprehensive
Blood Bank and
Immunohematology**
Price: \$350

Analytes:

ABO group
RhO (D) Group
Antibody detection
Antibody identification
Compatibility testing

Shipping Dates:

IM-1-04	3/04
IM-2-04	8/04
IM-3-04	11/04

Sample Type:

Each shipment will include five liquid serum and five RBC suspension samples.

Survey I101

**Limited
Immunohematology**
Price: \$210

Analytes:

ABO group
RhO (D) Group
Antibody detection

Shipping Dates:

IM-1-04	3/04
IM-2-04	8/04
IM-3-04	11/04

Sample Type:

Each shipment will include five liquid serum and five RBC suspension samples for determination limited to the level of testing performed on patient samples.

URINALYSIS

Survey U100+

**Dipstick
Urinalysis Only**
Price: \$35



Survey B110+

**Urine
hCG Only**
Price: \$25

Analytes:

Urinalysis (visual comparison and/or automated)
Specific Gravity Ketone
pH Bilirubin
Protein Hemoglobin (blood)
Glucose Leukocyte esterase
 Nitrite

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two liquid samples for semi-quantitative analysis of dipstick urine.

Analyte:

Urine hCG

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two liquid samples for qualitative determination.

URINALYSIS

Survey B111+

Sperm Count
Price: \$100

Analyte:

Sperm Count

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two stabilized semen samples for semi-quantitative determination.

Survey B114+

Urinalysis Combo
(Dipstick, hCG and
Urine Microscopic)
Price: \$75

Analytes:

Semi-quantitative analysis of dipstick constituents, qualitative determination of urine hCG and identification of microscopic constituents in urine

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two liquid samples for urine dipstick and hCG determinations as well as two 35mm transparencies for urine microscopic identification.

Survey B115+

Fecal Occult Blood
Price: \$25

Analyte:

Hemoglobin

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two liquid samples for use with guaiac, tablet and immunochemical methods for the qualitative determination of blood in stool.

MICROSCOPY



Survey B100+

Urine
Microscopy Only
Price: \$25

Analytes:

Identification of constituents in urine sediment

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two 35mm transparencies.

A 35MM SLIDE PROJECTOR OR HAND-HELD SLIDE VIEWER WITH MAGNIFICATION AND BACKGROUND LIGHT IS REQUIRED FOR EXAMINING B100, B102, B104 AND B112.

MICROSCOPY

Survey B101+

KOH Prep
Price: \$25

Analyte:

Presence or absence of fungal elements
in skin, hair and nails

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two microscopic slides.

Survey B102+

Pinworm Prep
Price: \$25

Analyte:

Presence or absence of pinworms
and/or pinworm eggs

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two 35mm transparencies.

Survey B104+

Sperm
Price: \$25



Analyte:

Presence or absence of spermatozoa

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two 35mm transparencies.

Survey B112+

Vaginal Wet Prep
Price: \$25

Analyte:

Presence or absence of elements indicative
of vaginal infection

Shipping Dates:

6/04
11/04

Sample Type:

Each shipment will include two 35mm transparencies.

+PARTICIPANT RESULTS FOR THESE SAMPLES WILL NOT BE REPORTED TO CMS. HOWEVER, PARTICIPATION WILL SATISFY CMS REQUIREMENTS FOR EXTERNAL ASSESSMENT OF ANALYTES NOT INCLUDED UNDER SUB-PART I, PROFICIENCY TESTING PROGRAMS SECTION 493.1709.

2004 PROFICIENCY TESTING SURVEY MAILING DATES

SURVEY	1/04	2/04	3/04	4/04	5/04	6/04	7/04	8/04	9/04	10/04	11/04	12/04
Throat Swabs (DAT)		2/23			5/3					10/25		
Throat Culture					5/4			8/3			11/8	
Syphilis				4/6				8/3				12/7
ASO, IM, HCG, ANA, Rubella Antibody & Rheumatoid Factor		2/3				6/8			9/28			
Chemistry & Lipids/Glucose Only Electrolytes Only			3/16				7/20				11/16	
Blood Gases				4/6			7/6				11/9	
Therapeutic Drugs			3/16				7/20				11/16	
Hematology (CBC & Cell ID) Coagulation & QBC		2/10				6/1				10/5		
Immunohematology & Limited Immunohematology			3/2					8/10			11/30	
Endocrinology			3/16				7/20				11/16	
EP	1/27				5/18				9/14			
Drugs of Abuse			3/9			6/15			9/21			

Please notify CLIS at 609-292-5605, Option #3, within 5 working days if you do not receive a scheduled shipment.
FAILURE TO DO SO WILL RESULT IN A RATING OF ZERO AND A “NON-PARTICIPATION” FOR THIS SURVEY.

**BIANNUAL ASSESSMENT PROGRAM (BAP)
2004 SHIPPING SCHEDULE**

<u>SURVEY</u>	<u>FIRST SHIPMENT</u>	<u>SECOND SHIPMENT</u>
Throat Screen (CLIA Waived DAT Methods only)	6/22/04	11/30/04
Dermatophyte Screen (DTM Agar)	6/22/04	11/30/04
<i>H. pylori</i> Antibody	6/22/04	11/30/04
Urine Culture (UC) Screen	6/22/04	11/30/04
Urine Culture Screen with Antibiotic Susceptibility Test	6/22/04	11/30/04
Dipstick Urinalysis only	6/22/04	11/30/04
Urine hCG only	6/22/04	11/30/04
Urine Microscopy only	6/22/04	11/30/04
Urinalysis Combo	6/22/04	11/30/04
Sperm Count	6/22/04	11/30/04
Sperm (Absence or Presence)	6/22/04	11/30/04
C-Reactive Protein (CRP)	6/22/04	11/30/04
PSA and/or PAP	6/22/04	11/30/04
Whole Blood Glucose (Waived Methods only)	6/22/04	11/30/04
Glycohemoglobin	6/22/04	11/30/04
GGT and/or Phosphorus	6/22/04	11/30/04
KOH Prep	6/22/04	11/30/04
Pinworm Prep	6/22/04	11/30/04
Vaginal Wet Prep	6/22/04	11/30/04
Sedimentation Rate	6/22/04	11/30/04
Coaguchek Prothrombin Time	6/22/04	11/30/04
Fecal Occult Blood	6/22/04	11/30/04

Please notify CLIS at 609-292-5605, Option #3, within 5 working days if you do not receive a scheduled shipment.